Clinical: Diagnosis and Outcome

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Clinical profile and treatment outcomes in patients receiving advanced therapies for ulcerative colitis – the READ-UC real-world study

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Background: Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) that requires effective treatment with the main goal of inducing and maintaining remission. This study aimed to characterize UC patients receiving advanced therapies (AT), by describing their demographic and clinical characteristics and remission outcomes.

Methods: Cross-sectional and retrospective study in 5 IBD referral centres. Eligible subjects (≥18 years-old with UC diagnosis and receiving AT for ≥16 weeks) were consecutively enrolled at a standard of care appointment (study appointment). The primary endpoints were the proportion of patients achieving remission, defined as both symptomatic [Mayo subscores stool frequency of 0 or 1 and rectal bleeding of 0] and faecal biomarker remission [faecal calprotectin <150 µg/g]. Data on patients' demographic and clinical characteristics, including extraintestinal manifestations (EIMs), comorbidities and treatment patterns, and on healthcare resource utilization were also collected.

Results: The study included 219 patients (50.9% female, median [P25;P75] age 46 [36;58] years) presenting a median disease duration of 9 [5;14] years. History or current evidence of EIMs and comorbidities were reported in 13.7% and 43.8% of patients, respectively. At diagnosis, 17.0% of patients had ulcerative proctitis, 38.1% had left-sided UC, and 44.8% had extensive UC. Over half (58.4%) were diagnosed with moderate or severe UC. Most patients (57.1%) were on their first AT, mostly on infliximab (47.5%) and vedolizumab (37.4%), while a minority received ustekinumab (5.9%), adalimumab (5.5%), tofacitinib (2.3%), and golimumab (1.4%). After treatment (26 [14; 47] months), symptomatic and faecal biomarker remission was achieved in 35.2% of patients, while 83.9% presented symptomatic remission and 46.1% of patients attained faecal biomarker remission (). There were no significant differences between patients who achieved symptomatic and faecal biomarker remission and those who did not (Table 1). Patients were prescribed concomitant specific therapies [5-ASA derivatives (78.0%), immunosuppressants (34.7%), and steroids (6.4%)]. Steroid-free remission was achieved in 34.9% of patients (Figure 1), who were off this medication for a median of 26 [15;45] months. Since AT initiation, 20.6% of patients relapsed, 11.9% were hospitalized, and 27.4% visited an emergency department.

Conclusion: The READ-UC study provides a detailed real-world characterization of UC patients on AT. The high proportion of patients not achieving symptomatic and faecal biomarker remission or steroid-free remission, highlights the urgent need for implementing strategies that improve UC management and outcomes of these patients.

Figure(s)/Table(s): see next page

Demographic and clinical characteristics	Remission Yes (n=69)	Remission No (n=127)
Age (years)		
Mean (SD)	45.0 (14.3)	48.3 (15.9)
Med [P25;P75]	45.0 [33.0;56.0]	49.0 [37.0;59.5]
Gender		
Female	32 (46.4%)	66 (52.4%)
Male	37 (53.6%)	60 (47.6%)
Missing	0	1
Smoking Status (*n*, %)		
Never tobacco smoker	33 (48.5%)	74 (60.2%)
Ex tobacco smoker	18 (26.5%)	25 (20.3%)
Current tobacco smoker	3 (4.4%)	5 (4.1%)
Not available	14 (20.6%)	19 (15.4%)
Missing	1	4
BMI (kg/m^2)		
Valid n (*Missing*)	68 (1)	115 (12)
Mean (SD)	25.6 (5.7)	25.6 (4.2)
Med [P25;P75]	24.4 [22.2;28.0]	24.9 [22.0;28.0]
Age at diagnosis of UC (years)		
Valid n (*Missing*)	69 (0)	127 (0)
Mean (SD)	34.7 (13.6)	37.2 (15.8)
Med [P25;P75]	34.0 [26.0;43.0]	35.0 [24.5;49.5]
UC disease duration (years)		
Valid n (*Missing*)	69 (0)	127 (0)
Mean (SD)	10.3 (8.1)	11.1 (8.8)
Med [P25;P75]	9.0 [5.0;13.0]	10.0 [5.0;15.0]
UC extent (Montreal classification) at diagnosis (*n*, %)		
E1	8 (14.5%)	19 (16.4%)
E2	23 (41.8%)	43 (37.1%)
E3	24 (43.6%)	54 (46.6%)
Missing	14	11
UC severity (Montreal classification) at diagnosis (*n*, %)		
S0	0 (0.0%)	2 (2.0%)
S1	14 (31.1%)	40 (40.4%)
S2	20 (44.4%)	36 (36.4%)
S3	11 (24.4%)	21 (21.2%)
Missing	24	28
Prior episode of ASUC at any time since diagnosis (*n*, %)		
Yes	21 (32.3%)	56 (44.8%)
No	44 (67.7%)	69 (55.2%)
Missing	4	2
Nr. of clinical relapses at study appointment since current treatment initiation (*n*, %)		
0 relapses	59 (85.5%)	90 (73.2%)
1 relapse	5 (7.2%)	26 (21.1%)
2 relapses	5 (7.2%)	3 (2.4%)
3 or more relapses	0 (0.0%)	4 (3.3%)

Table 1. Patients' demographic and clinical characteristics at study appointment, by remission status.

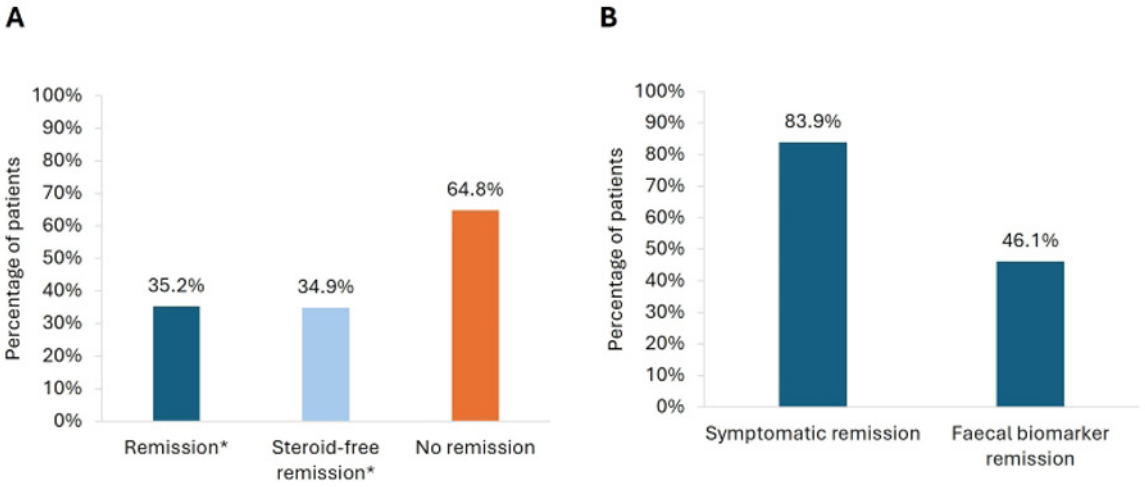

Figure 1. Remission status at study appointment, considering a faecal calprotectin (FC) cut-off concentration of <150 µg/g. **(A)**. Proportion of patients in remission at study appointment, defined by having achieved both symptomatic and FC remission and considering patients with both faecal biomarker remission and information on Mayo stool frequency and Mayo rectal bleeding subscores (n=69/196 (missing n=23)). Steroid-free remission: defined as both symptomatic remission and faecal biomarker remission without requiring steroid therapy (n=68/195 (missing n=24)). **(B)**. Symptomatic remission: defined by Mayo stool frequency subscore of 0 or 1 and Mayo rectal bleeding subscore of 0 (n=130/155 (missing n=64)). Faecal biomarker remission: defined by FC concentrations <150 µg/g (n=101/219). * *symptomatic and faecal biomarker remission*